UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. HEC PHARM CO., LTD., HEC PHARM USA, MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, ACCORD HEALTHCARE, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., ZYDUS PHARMACEUTICALS USA, INC., CADILA HEALTHCARE LTD., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICAL INC., INVAGEN PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL FZE, TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. 3:15-cv-5982-PGS-TJB (consolidated with Civil Action Nos. 3:16-cv-00852-PGS-TJB, 3:16-cv-00851-PGS-TJB, and 3:16-cv-02394-PGS-TJB) REPLY BRIEF IN SUPPORT OF RULE 12(c) MOTION TO DISMISS THE CLAIMS OF INFRINGEMENT OF U.S. PATENT NO. 8,853,156

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Defendants have clearly established that the '156 patent claims are directed to nothing more than the natural biological mechanism of DPP-4 inhibitors administered for any purpose. Boehringer's assertion in this case of earlier-expiring patents that already claim methods of using DPP-4 inhibitors to treat diabetes demonstrates that the '156 patent claims are not what Boehringer says they are. Boehringer does not dispute that renal impairment was long-known to be common in diabetics, that metformin was long-used to treat diabetes, and that it was commonly accepted that metformin should generally not be used in patients with renal impairment. Boehringer also does not dispute that DPP-4 inhibitors and linagliptin were previously known to be safe and useful in treating metabolic diseases and diabetics with renal impairment. Boehringer then "discovered" why DPP-4 inhibitors were safe in diabetics with renal impairment – because of their pharmacokinetic profiles. Through the '156 patent, Boehringer seeks to extend its previous monopoly by patenting knowledge of these pharmacokinetic profiles. This is not permitted under § 101. Addressing this legal issue now by dismissing the '156 patent from the case is permissible – and indeed desirable – because it will save time and expense and comports with good public policy.

ARGUMENT

I. The '156 Claims are Directed to Patent-Ineligible Subject Matter.

Boehringer implies that the Federal Circuit in *Rapid Litigation Management v. CellzDirect* came up with a new test to determine whether claims are directed to patent-ineligible subject matter based on "the end result of the process, the essence of the whole." *See* Pl. Br. (D. 354) at 9, 11-12. Actually, the court in *Rapid Litigation Management* simply found that the claims were directed to a "new and useful laboratory technique" to achieve a "new and useful end" rather than merely "observing or identifying the ineligible concept itself." *Rapid. Litig.*

Mgmt., Ltd., v. CellzDirect, Inc., 2016 WL 3606624, at *4.[1] Regardless of which language one uses, the '156 claims are directed to ineligible subject matter.

Boehringer's primary argument appears to be that the '156 patent claims are not directed to patent-ineligible subject matter because the administration of DPP-4 inhibitors alters the natural state of the body by inhibiting DPP-4 enzyme activity, which creates a chain of events that ultimately treats diabetes. *See* D. 354 at 11-12 and Pajvani Decl. (D. 354-1), ¶¶ 18-24.[2] But altering the natural state of the body by inhibiting DPP-4 enzyme activity is not the claimed invention. Rather, the language of the claims begins by reciting the use of DPP-4 inhibitors to treat metabolic diseases or diabetes—and *Boehringer does not dispute that this knowledge was already in the prior art*, as previously shown by Defendants. *See* Def. Op. Br. (D. 331) at 14-15, 17. Nor could it, because other prior art patents asserted against certain Defendants describe and recite the use of DPP-4 inhibitors to treat diabetes. *See* U.S. Patent Nos. 8,119,648 (Ex. 7), 8,178,541 (Ex. 8), and 9,173,859 (Ex. 9).[3] Indeed, Boehringer's expert, Dr. Pajvani, essentially echoes the '859 patent which – itself describing prior art – states that DPP-4 inhibitors "influence the plasma level of bioactive peptides including the peptide GLP-1 and are highly promising molecules for the treatment of diabetes mellitus." Ex. 9, col. 1:17-23.[4] But the purported "essence of the whole" of the '156 claims for a § 101 analysis is not what was already well

[1] The parties' references to *Rapid Litigation Management* and *Cellzdirect* are to the same case.

[2] Dr. Pajvani's opinions on legal matters are entitled to no deference by this Court.

[3] Unless noted "Ex." refers to exhibits attached to the Declaration of Philip L. Hirschhorn supporting this reply. All of these patents – incorporated by reference into the pleadings – state that the inventions relate to the administration of drugs that inhibit DPP-4 activity, and the claims recite their use in the treatment of diabetes. *See* Ex. 7 at Abstract and col. 106; Ex. 8 at Abstract and claim 15 (col. 131). Ex. 9 at Abstract and cols. 23-24.

[4] Dr. Pajvani explains that the '156 patent claims inhibit DPP-4 activity which results in "increased levels of GLP-1 and GIP hormones" that ultimately leads to a series of reactions lowering blood glucose levels. *See* D.354-1, ¶22.

known. Rather, the '156 patent specification tells the public that the invention is the supposed "finding" that certain DPP-4 inhibitors have "particularly advantageous properties" based on their pharmacokinetic properties. *See* Def. Op. Br. at 10-12; '156 patent (Ex. 1) at cols. 9, 13-14. These supposedly newly-discovered properties are what distinguishes the '156 claims from what is in the undisputed prior art. These newly-discovered properties (or a restatement thereof) are specifically recited and identified in the claims – which the Federal Circuit focused on as signaling claims directed to ineligible subject matter. *See Rapid Litig. Mgmt.,* 2016 WL 3606624, at *4. These properties are no more than an observation of the natural consequence of administering DPP-4 inhibitors. *See also Endo Pharms. Inc. v. Actavis Inc.,* No. 14-1381, 2015 WL 7253674, at *4 (D. Del. Nov. 17, 2015) (Rejecting claims under § 101 because there were no creative steps when the patent merely instructed doctors to apply a natural law: "Plaintiffs here claimed a widely-used, well-known method of treating pain. The only new aspect of the '737 patent was to tell doctors to adjust the dosage of oxymorphone based upon their discovery of a natural law—namely, how the bodies of individuals with renal deficiencies process the drug.").[5]

More importantly, Boehringer's argument that the '156 claims are directed to eligible subject matter because they recite administering a drug that alters the natural state of the body is also foreclosed by *Mayo*. There, the Federal Circuit originally held that the claims were patentable because administering the drug transformed the human body. *Mayo Collaborative Svcs. v Prometheus Labs., Inc.,* 132 S. Ct. 1289, 1296. (2012). The Supreme Court squarely rejected this argument, noting that:

[5] *Endo* rejected the argument that the claims were directed to patent-eligible subject matter simply because they recited methods of treating pain, noting that the patent specification there already explained that oxymorphone was widely used to treat pain, so the utilization of oxymorphone was not the invention. *See id.* at *3; *see also Endo v. Actavis*, 2015 WL 558048, at *6. The same holds true here, and *Rapid Litigation Management* does not change that.

> [w]hile it takes a human action (the administration of a drug) to trigger a manifestation of this [ineligible natural] relation in a particular person, *the relation itself exists in principle apart from any human action.* The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body – *entirely natural processes.*

Id. at 1297 (emphases added). The same holds here. Like the patent in *Mayo*, the '156 patent requires *administering* a drug, and like the natural relation recited in *Mayo*, the pharmacokinetic properties recited in the '156 claims exist apart from any human interaction and are a consequence of the way certain DPP-4 inhibitors are metabolized by the body – entirely natural processes.

Boehringer's remaining arguments for why the '156 patent claims are not directed to ineligible subject matter are unavailing. Boehringer argues that the recitation of the natural law in claim 11 simply narrows the scope of that claim to certain DPP-4 inhibitors. *See* D. 354 at 14. But even if true, this does not change the fact that Boehringer is claiming a natural law associated with the DPP-4 inhibitors covered by the claim. Similarly, Boehringer's reliance on two nonbinding memoranda from the USPTO quoting *dicta* from *Rapid Litigation Management* illustrates the dearth of legal support for Plaintiffs' position. At most, these authorities suggest that methods of treatment claims that apply steps that are more than "routine and conventional," Pl. Ex. 6 (D. 354-6) at 15, and do more than simply observe and identify a law of nature, Pl. Ex. 7 (D. 354-6) at 2, are patent eligible. But there is simply no rule of law that method of treatment claims are *per se* patent eligible, as Boehringer suggests. This is clear from *Mayo* where, like here, the claims involved therapeutic methods comprising *administering* a drug to individuals.

In the end, the '156 claims simply recite an observed property inherent to previously-known methods. It is telling that Plaintiffs admit that the '156 patent claims simply *"relate to"* an alleged "revolutionary new method of treating or preventing" diabetes – not that they actually

claim it. D. 354 at 6. Indeed, the '648 patent asserted by Plaintiffs – which expires nearly eight years before the '156 patent – already claims a method of treating diabetes with linagliptin. In other words, even if a method for treating diabetes with linagliptin is patent eligible, that "invention" is not claimed by the '156 patent. Rather, the '156 patent claims the observation that certain DPP-4 inhibitors are metabolized in the liver and not the kidneys. That observation is directed to patent-ineligible subject matter under *Mayo* and *Endo*.

II. There is No Material Factual Dispute that the '156 Patent Claims Recite Conventional, Routine, and Well-Understood Activities.

Boehringer does not dispute that § 101 challenges can be an appropriate basis for judgment on the pleadings. *See, e.g., OIP Techs., Inc. v. Amazon.com, Inc.,* 788 F.3d 1355, 1360 (Fed. Cir. 2015). Nor does Boehringer dispute that the specification of the '156 patent – incorporated by reference into the pleadings – acknowledges the following was known in the prior art:

- Metformin was used to treat diabetes;
- Metformin was contraindicated in patients with renal impairment;
- DPP-4 inhibitors and linagliptin could be used to treat metabolic diseases and diabetes;
- Nephropathy and renal impairment was common in diabetics; and
- DPP-4 inhibitors could be used to treat diabetics with nephropathy and renal impairment.

Dr. Pajvani's declaration also does not dispute any of these facts. These are all the facts necessary for the Court to decide Defendants' motion, because these facts represent all of the other limitations in the claims besides the patentee's observations of natural laws. These undisputed facts demonstrate that the second step of the *Alice/Mayo* inquiry has been met: they recite conventional, routine, and well-understood activities.

A. Boehringer incorrectly conflates § 101 with obviousness.

Boehringer attempts to conflate this second step of the *Alice/Mayo* framework with the obviousness inquiry under § 103 in order to argue that judgment on the pleadings is improper

without discovery. D. 354 at 18-19. However, Boehringer's argument contradicts *Mayo*. There, the Solicitor General urged the Court to adopt a narrow interpretation of § 101 that would render most methods patent-eligible, on the grounds that patentability issues were better addressed by other statutory provisions including § 103. *See Mayo*, 132 S. Ct. at 1303-04. The Court squarely rejected this argument, noting that even though the analyses may overlap, the inquiry under § 101 was separate and distinct from these other provisions. *See Mayo*, 132 S. Ct. at 1304. Indeed, the § 103 inquiry involves, for example, additional inquiries into secondary considerations, whereas the § 101 does not. The bottom line is that no discovery is needed to ascertain what the '156 patent already admits and Boehringer does not dispute.

B. Dr. Pajvani's declaration does not create a material factual dispute.

Boehringer attempts to manufacture a factual dispute as to whether the remaining limitations of the '156 patent are "inventive" (*i.e.,* address more than routine, conventional, and well-understood activities) through a legally irrelevant declaration from Dr. Pajvani. Dr. Pajvani opines that claim 10 is "inventive" because linagliptin requires no dosage adjustment for all patients regardless of the degree of renal impairment, which supposedly means that "labor intensive" monitoring of renal function is no longer needed and patients have a new treatment option. D. 354-1 at ¶¶ 28-29, 33. Boehringer then extends this opinion to the entire patent to proclaim that it "*addresses the foregoing needs*" of patients. *See* D. 354 at 19-20 (emphasis added). But this is an argument based on supposed long felt need – that is, irrelevant *secondary considerations of nonobviousness,* and not whether the limitations themselves recite routine, conventional, and well-understood activities.

Assuming Boehringer's assertions are true (and Defendants do not agree), the Federal Circuit already has rejected an argument similar to Boehringer's. In *Ariosa Diagnostics, Inc. v.*

Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), the inventors discovered that cell-free fetal DNA existed within maternal plasma and serum, thereby creating a new way to conduct prenatal diagnostic testing based on a simple blood draw from the mother rather than risky fetal or placental blood sampling. *See id*. at 1373. The court accepted as true that the discovery of cell-free fetal DNA in maternal blood samples was "surprising and unexpected[,]" *id.* at 1376, and that the claimed method "revolutionized prenatal care" because no one previously used maternal blood samples for prenatal testing, *id.* at 1379. Still, the claims were invalid under § 101 because the existence of cell-free fetal DNA was a natural phenomenon and the testing methods described were routine and conventional. *See id.* at 1376-78. As the Federal Circuit explained, "the Supreme Court instructs that groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Id*. at 1379, citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2117 (2013) (internal quotations and brackets omitted). Here, it does not matter whether the inventions claimed in the '156 patent met a supposed long felt need to take a medication without monitoring renal function. As the Federal Circuit noted in *Ariosa*, "this is not the invention claimed" by the patent. *Ariosa*, 788 F. 3d at 1379.

III. No Remaining Issues Preclude Judgment on the Pleadings.

A. Claim construction is not necessary to resolve Defendants' motion.

Boehringer asserts that it was somehow hoodwinked into dropping certain claims from the case and would otherwise have offered plausible constructions for those claims. *See* D. 354 at 23. Boehringer has not been prejudiced in any way and its assertion is misleading at best. Boehringer dropped certain previously asserted claims of the '156 patent on March 22, 2016. *See* Gannon Decl. (D. 354-5), ¶ 4 and Gannon Exhibit 2 (D. 354-6). Boehringer served this document accompanied by an email from its counsel stating that "Plaintiffs reserve[] the right to modify the

asserted claims as appropriate as discovery in this case continues." *See* Hirschhorn Decl. Ex. 10 (3/22/16 email from Mulvaney to Defendants' counsel). This email reserving rights was omitted from Boehringer's supporting declaration. Further, as Boehringer acknowledges, Defendants provided Boehringer with their proposed § 101 amendment on May 13 – well before the claim construction identification and negotiation process began. In fact, the claim construction process began about one month later on June 10, the joint claim construction statement was not filed until July 24, and opening briefs were not filed until August 17. Thus, Boehringer had plenty of time to consider and incorporate the impact of Defendants' § 101 argument on its claim construction position and plenty of time to re-assert certain claims if it believed they were affected by Defendants' argument. It did not do so. In fact, Boehringer completely changed its claim construction position on the meaning of the '156 term patent "metabolic disease" in the middle of this negotiation process – demonstrating that it was fully capable of adjusting its positions if need be. *See* Ex. 11 (comparing Boehringer's June 24 disclosure with its July 8 disclosure). Boehringer's assertion that it was helpless to do anything as Defendants supposedly duped them is untrue.

Boehringer also asserts that under *Data Distribution Technologies, LLC v. BRER Affiliates, Inc.,* No. 12-4878, 2014 WL 4162765 (D.N.J. Aug. 19, 2014), Defendants must address every plausible construction of each claim before claim construction. D. 354 at 21-22. However, the Court there expressly stated that claim construction is not mandatory to address a § 101 motion, but it depends upon the facts of the individual case. *See Data Distribution,* 2014 WL 4162765 at *5. Further, the defendants were required to address every plausible construction only because the parties had not yet exchanged claim terms or provided proposed constructions at the time the § 101 motion was filed; the Court stated that if proposed constructions had been

exchanged, it would have simply considered the motion in light of the plaintiffs' proposed constructions. *See id.* at *7-*8. Here, however, the parties *have* already exchanged and briefed disputed claim constructions, so *Data Distribution* does not apply.

Further, even accepting Boehringer's proposed constructions, there are no claim construction issues precluding judgment for Defendants. Boehringer asserts that a dispute over the construction of claim 10 precludes judgment for Defendants, but fails to explain why a § 101 analysis depends upon this dispute – because it does not. In claim 10, Boehringer contends that the final "wherein" limitation refers to DPP-4 inhibitors in which the dosage does not need to be adjusted for *all* degrees of renal impairment, whereas Defendants contend that the limitation refers to DPP-4 inhibitors in which the dosage does not need to be adjusted for *some* degrees of renal impairment. D. 345 at 14-15. The dispute may be relevant to other invalidity issues, but that does not affect the question whether the claim is directed to a natural law, because the ability to not adjust the dosage is simply an observation – a consequence of the fact that whatever DPP-4 inhibitor being administered is not eliminated primarily through the kidney. Nor does this claim construction dispute affect whether the other steps involved are routine, conventional, or well-understood. It is simply irrelevant to the § 101 analysis.

The only other claim construction issue Boehringer can muster up is the suggestion that if it had known about Defendants' § 101 contentions (which it did), it would have asked the Court to construe "DPP-IV inhibitor" to refer to a small molecule that is foreign to the body that performs a function that is not naturally performed. D. 354 at 24. But this is not a claim construction issue – it is simply a restatement of what Boehringer asserts to be a relevant legal issue for a § 101 analysis. Boehringer cannot use circular reasoning to recast its § 101 legal argument as a claim construction argument and then assert that the Court cannot address the

§ 101 legal argument because it pertains to claim construction.

In the end, even accepting Boehringer's proposed constructions as true, the fact that Boehringer cannot provide a single meaningful example of how a disputed claim construction issue would preclude judgment at this time demonstrates that there are none.

B. Defendants have shown that every claim is patent ineligible.

Contrary to Boehringer's assertions, D. 354 at 21-22, Defendants addressed every single claim in the '156 patent. The fact that some claims were addressed in footnotes because the analysis varied little from the analysis in the text of Defendants' brief is immaterial.

C. Defendants' motion is procedurally proper.

Boehringer does not dispute that the plain text of Rule 12(c) permits Defendants to bring this motion and that local patent rules as applied cannot be inconsistent with the Federal Rules. "After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). That alone makes Defendants' motion procedurally proper. Instead, Boehringer cites broad *dicta* from *O2 Micro International Ltd. v. Monolithic Power Systems, Inc.* to contend that the Federal Rules are not inconsistent with requiring a showing of diligence to amend patent contentions. D. 354 at 25. That is beside the point.

Defendants' motion is consistent with *O2 Micro*. *O2 Micro* concerned an appeal of a district court's discretionary decision not to allow O2 Micro to amend its infringement contentions because it had supposedly discovered new evidence, on the grounds that O2 Micro was not diligent in seeking the amendment and its opponent would be prejudiced. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.,* 467 F.3d 1355, 1361-62 (Fed. Cir. 2006). On appeal, O2 Micro contended as a blanket rule that whenever a party uncovers new evidence in discovery it

should be allowed to amend its contentions as long as it does so within a reasonable period after discovery closes. *Id.* at 1363. The Federal Circuit rejected O2 Micro's *per se* argument, noting that the Federal Rules allowing for liberal discovery were not inconsistent with requiring O2 Micro to show diligence in amending its contentions. *See id.* at 1366. That is as far as the case goes. In its reasoning the Federal Circuit acknowledged – as Defendants previously noted – that the application of local rules could be inconsistent with the Federal Rules, particularly where the parties were locked into their positions "at the outset of the case, shortly after the pleadings were filed[.]" *See id.*

Defendants' motion addresses a different issue than that relied upon by Boehringer from *O2 Micro*. Defendants assert that under the facts of this case, refusing to consider Defendants' motion at this time would plainly be inconsistent with Rule 12(c). Rule 12(c) allows Defendants' motion because the pleadings are closed and it will not delay trial. Further, the purpose of the Rule is to save time and expense when, like here, a pure legal issue can be resolved. This purpose for the Rule and the lack of prejudice to Boehringer are consistent with the fact that the Court can address a dispositive legal issue at this early stage without it being addressed in Defendants' original contentions – which is the point made by *Mobile Telecommunications Technologies, LLC v. United Parcel Service, Inc.,* -- F. Supp. 3d --, No. 12-322, 2016 WL 1171191 (N.D. Ga, Mar. 24, 2016), regardless whether that court's local rules are identical to this Court's. The facts in this case fit within circumstances contemplated by the Federal Circuit in *O2 Micro* when it noted that locking parties into contentions too early would be improper.

Lastly, Boehringer relies heavily on two non-binding cases from the Northern District of California. Defendants already previously distinguished those cases, which Boehringer fails to address. In *Good Technology Corp. v. Mobileiron, Inc*, No. 12-05826, 2015 WL 3866019 (N.D.

Cal. May 4, 2015), the case had apparently been proceeding for approximately three years, discovery was "complete" and trial was only "two months away." *Id.* at *2. The party seeking dismissal had never previously informed the patentee of its § 101 defense. *Id.* Similarly in *Radware, Ltd. v. F5 Networks, Inc.,* 147 F. Supp. 3d 974 (N.D. Cal. 2015), the moving party waited over one and a half years after serving original contentions to file its Rule 12(c) motion and had not previously informed the patentee of its defense. *Id.* at 981-82. Neither of these cases presents circumstances similar to this case and neither of these cases considered the argument that its application of local rules might be inconsistent with the Federal Rules. They are inapposite here.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion to dismiss the '156 patent from the case.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing Reply Brief in Support of Rule 12(c) Motion to Dismiss the Claims of Infringement of U.S. Patent No. 8,853,156 and the Declaration of Philip L. Hirschhorn in Support of Reply Brief on Rule 12(c) Motion to Dismiss the Claims of Infringement of U.S. Patent No. 8,853,156 were caused to be served on September 1, 2016 via email upon all counsel of record.

Dated: September 1, 2016

/s/ Philip L. Hirschhorn
Philip L. Hirschhorn